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DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Tablet/Bolus

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Boehringer Ingelheim Vetmedica, Inc. The NADA provides for use of oxytetracycline boluses for control and treatment of bacterial enteritis and bacterial pneumonia in beef and dairy calves.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002, filed NADA 141–002 that provides for use of Oxy 500 and 1,000 Calf Boluses (oxytetracycline hydrochloride boluses) for control and treatment of bacterial diseases of beef and dairy calves caused by organisms sensitive to oxytetracycline, bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida*. The NADA is approved as of October 26, 1998. The regulations are amended in 21 CFR 520.1660c by revising the section heading, paragraphs (a) and (b), by removing an outdated paragraph (c), by redesignating paragraphs (d) and (e) as paragraphs (c) and (d), and by amending paragraph (d)(3) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1660c is amended by revising the section heading, by revising paragraphs (a) and (b), by removing paragraph (c), by redesignating paragraphs (d) and (e) as paragraphs (c) and (d), and by revising the 4th sentence in newly redesignated paragraph (d)(3) to read as follows:

§ 520.1660c Oxytetracycline hydrochloride tablets/boluses.

(a) *Specifications.* Each tablet or bolus contains 250, 500, or 1,000 milligrams of oxytetracycline hydrochloride.

(b) *Sponsors*. For sponsors in § 510.600(c) of this chapter: See 000010 for use of 500 and 1,000 milligram boluses. See 000069 for use of 250 and 500 milligram tablets.

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(d) * * *

(3) * * * For sponsor 000069: Discontinue treatment 7 days prior to slaughter. * * *

Dated: 11/30/98

November 30, 1998

SFS

Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 98–???? Filed ??–??–98; 8:45 am]

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